Results of the SORT-OUT VI trial presented

30 October 2013

A new study found that both drug-eluting stents (DES) with biocompatible polymers and DES with biodegradable polymers were associated with low major adverse coronary events, demonstrating the non-inferiority of the biocompatible polymer stents in patients undergoing percutaneous coronary intervention (PCI). The findings of the SORT-OUT VI trial were presented today at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Compared with bare metal stents, first generation DES reduced the risk of restenosis. However, the risk of stent thrombosis was a concern and newer generation DES have been designed to improve efficacy, safety, and device performance. To date, there are no large scale randomized comparison studies of biodegradable polymer-coated stents and biocompatible polymer-coated stents in all-comer populations. The SORT-OUT VI trial investigated the safety and efficacy of a durable but biocompatible polymer coated zotarolimus-eluting stent compared with a biodegradable polymer-coated biolimus-eluting stent in a population-based setting.

SORT-OUT VI was a multicenter, all-comer, non-inferiority trial that randomized 2,999 patients with stable coronary artery disease or acute coronary syndromes. The trial was performed within the framework of the Scandinavian Organization for Randomized Trials with Clinical Outcomes, and used patient-driven clinical event detection through Danish health care registries.

Patients were randomized to receive either a zotarolimus-eluting permanent polymer stent (n=1,502) or a biolimus-eluting biodegradable stent (n=1,497). The primary endpoint was a composite of major adverse cardiac events including cardiac death, myocardial infarction, and target lesion revascularization after 12 months.

After 12 months the percentage of patients with major adverse cardiac events was similarly low in both the zotarolimus-eluting and biolimus-eluting stent groups (5.3 percent and 5.1 percent, respectively), demonstrating the non-inferiority of the zotarolimus-eluting stent.

"The SORT OUT VI trial found that both zotarolimus-eluting and the biolimus-eluting stents were associated with low major adverse cardiac events," said lead investigator Bent Raungaard MD. Dr. Raungaard is Chief Physician and Associate Professor at Aalborg University Hospital in Denmark.

"Further, the zotarolimus-eluting stent was found to be non-inferior to the biolimus-eluting stent for patients treated with PCI."

Provided by Cardiovascular Research Foundation

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